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GOTTLIEB RACKMAN & REISMAN PC
270 MADISON AVENUE
8TH FLOOR
NEW YORK, NY 100160601

EXAMINER

DROESCH, KRISTEN L

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,377

Applicant(s)

BARDY ET AL.

Examiner

Kristen L Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/30/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 and 75-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 18-20, 23, 24, 26, 28-74, 80-84, 87, 88, 90 and 92-109 is/are rejected.
- 7) ☒ Claim(s) 21, 22, 25, 27, 85, 86, 89 and 91 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/27/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species VII in Paper No. 8 is acknowledged.
2. Claims 13-17, and 75-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Drawings

3. The drawings are objected to because in Figure 23 B element number 228 is missing and not shown as it is in Fig. 23A. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims, 25 47, and 89 are objected to because of the following informalities: misspelling "inframmary" should be inframammary. Appropriate correction is required.
5. Claim 101 is objected to because of the following informalities: missing verb. Appropriate correction is required. The examiner suggests --...electrode is disposed...".

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 10, 12, 30-62, and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 2 recites the limitation "the canister" in line 1. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests amending claim 2 to be dependent on claim 1.

Claim 10 recites the limitation "the width" in line 1. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests changing the wording of each claim to be similar to claim 11.

Claims 12, 30 31, 61-62, and each recite the limitation "the length" in line 1. There is insufficient antecedent basis for these limitations in these claims. The examiner suggests changing the wording of each claim to be similar to claim 11.

Claim 32 recites the limitation "... advancing the ICD through the single incision and subcutaneously over approximately a patient's third rib *and* approximately a patient's twelfth rib." Why would the canister need to be advanced over both the third rib and the twelfth rib to rest adjacent to either the third or twelfth rib? Wouldn't the surgical incision be made proximate to where the implant was to be inserted, thereby avoiding the necessity of advancing the canister subcutaneously over such a large distance between the third and twelfth ribs? The examiner believes that the applicant intended to claim to read -- "... advancing the ICD through the single incision and subcutaneously over and *between* approximately a patient's third rib and approximately a patient's twelfth rib.--

Claim 82 recites the limitation "the electrical circuit" in line 2. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests changing the wording of each claim to be similar to claim 11.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1- 12, 18-20, 24, 28-31, 63 -74, 80-81, 84, 88, 90, and 92-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (5,292,338) in view of Meltzer (5,645,586) and further in view of Sanchez-Zambrano (5,895,414).

Regarding claims 1 and 80, Bardy shows a method of inserting an implantable cardioverter defibrillator comprising providing an ICD canister, making a single incision into the patient (Abs) and advancing the ICD canister through the single incision and subcutaneously over the patient's ribcage (Abs; Col. 3, line 57-Col. 4, line 12). Although Bardy fails to specifically state that the ICD is implanted subcutaneously over the patient's ribcage, it is inherent that the ICD implanted subcutaneously in the pectoral region is also implanted over the patient's ribcage due to the anatomical configuration of the human body.

Although Bardy fails to teach that the ICD canister is non-planar to maintain the cardioverter in a predetermined relationship with to a patient's heart, over the patient's ribcage, attention is directed to Meltzer which teaches an ICD canister that is adapted to follow the contours of the pectoral region of the patient's body either by a flexible housing or hinges. Meltzer teaches that this modification minimizes skin dislocation, protrusions, irritation, medical complications, obtrusiveness, and patient discomfort (Col. 1, line 38-Col. 2, line 2).

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Although Bardy and Meltzer fail to teach that the ICD canister is non-planar, attention is directed to Sanchez-Zambrano which teaches a pacemaker housing (canister) that is non-planar and addresses the same deficiencies that the Meltzer device addresses. Sanchez-Zambrano teaches that the pacemaker housing is contoured to the natural curvature of the patient's ribs to fit smoothly under the skin and against the ribcage (Col. 1, lines 22-26), thereby avoiding the discomfort, unsightly bulges, and high stress zones on the skin of the prior art (Col. 1, lines 11-18).

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Bardy with a conformable ICD canister of Meltzer in order minimize skin dislocation, protrusions, irritation, medical complications, obtrusiveness, and patient discomfort, and further it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Bardy modified with the ICD canister of Meltzer with an canister that is non-planar and contoured to the natural curvature of the patient's ribs to fit smoothly under the skin and against the ribcage as Sanchez-Zambrano teaches in order to avoid discomfort, unsightly bulges, and high stress zones on the skin.

Regarding claims 2-8, and 64-70, Bardy, Meltzer, and Sanchez-Zambrano disclose the claimed invention except for the specific dimensions of the housing. It would have been an obvious matter of design choice to size the length of the canister less than 30 cm, approximately 3 cm to 30 cm long, approximately 5 cm to 20 cm long, or approximately 5 cm to 12 cm long, the width of the canister to be approximately 3 cm to 10 cm wide, or approximately 3 cm to 6cm wide, the depth of the canister to be less than 15 mm since such a modification would have

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involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

With respect to claims 9, and 71, Bardy, Meltzer, and Sanchez-Zambrano show the canister comprises a first end and a second end (Fig. 1 of Bardy, Fig. 2 of Meltzer, Fig. 1 of Sanchez-Zambrano).

Regarding claims 10, and 72, Bardy and Meltzer show the width of the canister between the first and second end are substantially similar (Fig. 1 of Bardy, Fig. 2 of Meltzer).

With respect to claims 11, and 73, Meltzer shows a length of the canister is greater than a width of the canister (Fig. 2).

Regarding claims 12, and 74, Bardy shows a length of the canister is substantially similar to a width of the canister (Fig. 1).

With respect to claims 18, 19, 63, and 96, Bardy shows the canister further comprises an electrode located on a surface portion of the canister that can emit a shocking energy and an electrical circuit (Fig. 2) located within the housing (Abs).

With respect to claims 20 and 84, Bardy shows a portion of the canister comprises an electrically insulated material (Col. 3, lines 46-57).

Regarding claims 24, 88, and 90, Bardy, shows the canister is advanced proximate a patient's heart and sternum.

With respect to claims 28-29, 92-93, Bardy, Meltzer, and Sanchez-Zambrano show the canister refrains from directly contacting the patient's heart or intrathoracic vasculature (Fig. 1 of Bardy, Fig. 12 of Meltzer, Figs 4-7 of Sanchez-Zambrano).

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Regarding claims 30-31, and 94-95, Meltzer shows the length of the defibrillator is oriented along the length of the ribs (Figs. 1, 5) and Bardy shows the length of the defibrillator is oriented perpendicularly to the length of the ribs (Fig. 1).

With respect to claim 81, Bardy shows the electrode is located on a portion of the first end of the housing (Fig. 1).

Regarding claims 97-98, Bardy shows the housing has an elongated shape (top to bottom in Fig. 1) with two opposed ends and the electrode (11) is disposed adjacent to one end and is disposed at one end (Fig. 1).

With respect to claims 99-100, and 107-108, Bardy shows the electrode (11) is substantially rectangular and has a generally square shape with rounded corners (Fig. 1).

Regarding claims 101-102, Bardy shows the electrode (11) is disposed transversally to a longitudinal axis and is disposed substantially along a width (Fig. 1)

With respect to claims 103-106, Bardy, Meltzer, and Sanchez-Zambrano disclose the claimed invention except for the electrode being triangular shaped with rounded corners with the right angle disposed at the corner of the housing. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the shape of the electrode as taught by Bardy, Meltzer, and Sanchez-Zambrano s with a electrode being triangular shaped with rounded corners where the right angle is disposed at the corner of the housing, since applicant has not disclosed that the triangular shaped electrode with rounded corners and a right angle disposed at the corner of the housing provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape electrode such as the rectangular or square electrode taught by Bardy for applying defibrillation energy. A change in

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shape absent persuasive evidence of the significance of the configuration has been held to be a matter of obvious design choice to one with ordinary skill in the art. See *In re Dailey*, 357 F.2d 669 (CCPA 1966).

Regarding claim 109, Bardy, Meltzer, and Sanchez-Zambrano disclose the claimed invention except for the electrode being spaced away from the longitudinal sides of the housing. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the shape of the electrode as taught by Bardy, Meltzer, and Sanchez-Zambrano with a electrode being spaced away from the longitudinal sides of the housing, since applicant has not disclosed that an electrode being spaced away from the longitudinal sides of the housing provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape electrode such as the rectangular or square electrode taught by Bardy for applying defibrillation energy. A change in shape absent persuasive evidence of the significance of the configuration has been held to be a matter of obvious design choice to one with ordinary skill in the art. See *In re Dailey*, 357 F.2d 669 (CCPA 1966).

10. Claims 23, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (5,292,338) in view of Meltzer (5,645,586) and Sanchez-Zambrano (5,895,414) as applied to claims 1, and 81. Bardy, Meltzer, and Sanchez-Zambrano are as explained before. Although Bardy, Meltzer, and Sanchez-Zambrano fail to specifically show a step of shaping a passageway within the patient for the ICD to navigate, it is well known in the art that ICD's are implanted in surgically formed passageways (pockets) in the chest. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to shape a passageway

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within the patient for the ICD to navigate since it is well known. See for example Alt (6,076,014; Col. 4, lines 55-57) and Kroll (6169,923; Col. 4, lines 13-15).

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (5,292,338) in view of Meltzer (5,645,586) and Sanchez-Zambrano (5,895,414) as applied to claim 1. Bardy, Meltzer, and Sanchez-Zambrano are as explained before. Although Bardy, Meltzer, and Sanchez-Zambrano fail to specifically show advancing the canister towards the sternum, the direction of advancement would depend on whether the incision made was to the left or right, or above or below the location of the intended placement of the ICD, thus being a matter of obvious design choice. Therefore, it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to advance the canister through the single incision subcutaneously over the rib cage and towards the sternum and advanced toward the sternum.

12. Claims 82-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (5,292,338) in view of Meltzer (5,645,586) and Sanchez-Zambrano (5,895,414) as applied to claim 81, and further in view of Hauser et al. (5,713,926). Bardy, Meltzer, and Sanchez-Zambrano are as explained before. Although Bardy, Meltzer, and Sanchez-Zambrano fail to teach a second electrode located on a portion of the second end of the housing and electrically coupled to a circuit within the housing, attention is directed to Hauser et al. which teaches a defibrillator with first (62) and second (64) electrodes each located on the first and second ends of the housing respectively (Fig. 11). Hauser et al. teaches that this configuration enables one or two of the electrodes (of three) to be dedicated for sensing purposes while the others may be dedicated for shocking purposes (Col. 6, lines 51-58). Therefore, it would have been obvious to

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one with ordinary skill in the art at the time the invention was made to modify the device of Bardy, Meltzer, and Sanchez-Zambrano with first and second electrodes each located on the first and second ends of the housing respectively as Hauser et al teaches in order to enable one or two of the electrodes to be dedicated for sensing purposes while the others may be dedicated for shocking purposes

Allowable Subject Matter

Don't forget claims that have been objected to

13. Claims 32-62 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

With respect to claims 32-62, the prior art of record fails to teach or suggest a method of implanting a defibrillator which includes advancing the defibrillator subcutaneously over and between approximately the patient's third and twelfth ribs. It is well known in the art to implant defibrillators in a pectoral region and typically located just below the clavicle. See Kroll (6,169,923 Col. 4, lines 13-15). Purdy (3,987,799) shows the location of an implantable pacemaker in relation to the human anatomy of the chest. The pacemaker is located below the clavicle (29) and over approximately the first and second ribs (22). Likewise, Sanchez Zambrano shows the pacemaker located between the clavicle (21) and the third rib (27) (Col. 1, lines 63-66).

14. Claims 21-22, 27, 85, 86, 89, and 91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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15. Claim 25 would be allowable if rewritten to overcome the claim objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

With respect to claims 21 and 85, the prior art of record fails to teach or suggest a method of inserting an ICD comprising providing an ICD with at least a non planar portion or configured to maintain the canister in a predetermined relationship with respect to a patient's heart; making a single incision into the patient; advancing the ICD through the single incision and subcutaneously over a patient's ribcage in combination with the single incision being made approximately at the level of the cardiac apex.

Regarding claims 22, and 86, the prior art of record fails to teach or suggest a method of inserting an ICD comprising providing an ICD with at least a non planar portion to maintain the canister in a predetermined relationship with respect to a patient's heart; making a single incision into the patient; advancing the ICD through the single incision and subcutaneously over a patient's ribcage in combination with the single incision being made approximately in the left anterior axillary line.

With respect to claims 25, and 89, the prior art of record fails to teach or suggest a method of inserting an ICD comprising providing an ICD with at least a non planar portion to maintain the canister in a predetermined relationship with respect to a patient's heart; making a single incision into the patient; advancing the ICD through the single incision and subcutaneously over a patient's ribcage in combination with the ICD being advanced medially toward a patient's left inframamary crease.

Regarding claims 27, and 91, the prior art of record fails to teach or suggest a method of inserting an ICD comprising providing an ICD with at least a non planar portion to maintain the

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canister in a predetermined relationship with respect to a patient's heart; making a single incision into the patient; advancing the ICD through the single incision and subcutaneously over a patient's ribcage in combination with the ICD being advanced approximately between a patient's third and twelfth rib.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Muto (4,094,321) shows a pacemaker canister with a non-planar surface. Schroepfel (5,776,169) shows a pacemaker for subcutaneous implantation. Laird et al (6,445,956) shows an implantable device with a non-planar surface

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



kld



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700